UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,717	02/19/2002	Kenj Asano	0203-0162P	3321

2292 7590 08/17/2006

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
TATE, CHRISTOPHER ROBIN	
ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 08/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/856,717	ASANO ET AL.	
	Examiner	Art Unit	
	Christopher R. Tate	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-32 and 34-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-32 and 34-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The response filed 05 June 2006 is acknowledged and has been entered. Claims 24-32 and 34-38 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 24, 25, and 35-38 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Nagaoka (US 6,090,615) and Nagaoka (US 2004/0038330 - which has an effective filing date of June 9, 1994) for the reasons set forth in the previous Office action which are restated below.

The US '615 reference teaches a *Lentinus edodes* (also known as shiitake mushroom) mycelium (hyphae) extract which is prepared via the same (or essentially the same) steps as instantly claimed, as well as pharmaceutical, drink, oral (food) formulations thereof, and a method of treating tumors therewith (see, e.g., col 1, lines 30-44; col 2, lines 25-63; col 3, lines 6-68; and Example 1, Comparative Examples 1 and 2, Example 4, Comparative Examples 3-4).

In addition, the US '330 reference teaches a *Lentinus edodes* mycelium extract, prepared via the same (or essentially the same) steps as instantly claimed, which is useful against liver cancer (see, e.g., claim 5).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a therapeutic anti-tumor/anti-cancer *Lentinus edodes* (shiitake) mycelium extract via the instantly claimed steps, including formulating such therapeutic extracts

into conventional pharmaceutical, drink, and/or oral (e.g., food) preparations, as well as to treat liver cancer (which is typically a tumorous-type cancer) and/or other tumors therewith, based upon the beneficial teachings provided by the cited Nagaoka references with respect to such anti-tumor/anti-cancer activity. Please note, if not expressly taught, the other claim limitations (e.g., that the extract has a particular functional cell activity and/or that it comprises approximate ranges of various ingredients therein) would be intrinsic to the *Lentinus edodes* mycelium extracts taught by US '615 and US '330. The result-effective adjustment in conventional working conditions/parameters (e.g., providing such an extract within one or more conventional pharmaceutical formulations such as those instantly claimed) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan having the cited references as a guide.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 26, 27, 30-32, 34 and 38 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Nagaoka (US 2004/0038330) for the reasons set forth in the previous Office action which are restated below.

The cited reference teaches a *Lentinus edodes* (also known as shiitake mushroom) mycelium (hyphae) extract which is prepared via the same steps as instantly claimed, as well as

pharmaceutical, drink, oral (food) formulations thereof, and a method of treating viral diseases such Hepatitis B, as well as HIV therewith (see, e.g., paragraphs [0009], [0010], [0015] - [0042] and claims).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a therapeutic anti-viral *Lentinus edodes* (shiitake) mycelium extract via the instantly claimed steps, including formulating such therapeutic extracts into conventional pharmaceutical, drink, and/or oral (e.g., food) preparations, as well as to treat viral infections therewith (such as those instantly claimed, including Hepatitis B and other viral infections), based upon the beneficial teachings provided by the cited reference with respect to such anti-viral activity. Please note that the other claim limitations (e.g., that the extract has a particular cell functional activity and/or that it comprises approximate ranges of various ingredients therein) would be intrinsic to the *Lentinus edodes* mycelium extract taught by US '330. The result-effective adjustment in conventional working conditions/parameters (e.g., providing such an extract within one or more conventional pharmaceutical formulations such as those instantly claimed and/or treating a particular type of viral infection - especially given that no demonstrated working examples have been provided within the instant disclosure with respect to treating a particular type of viral infection, including those instantly claimed) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over the cited reference, especially in the absence of evidence to the contrary.

Claims 26-29 and 38 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Nagaoka (JP 61103816 - JPAB and DWPI Abstracts) for the reasons set forth in the previous Office action which are restated below.

The cited reference teaches a *Lentinus edodes* (also known as shiitake mushroom) mycelium extract having antibacterial (antibiotic) activity (thus, useful for treating bacterial infections), which is prepared via the same (or essential the same) steps as instantly claimed, as well as pharmaceutical (e.g., cream) formulation thereof (see, e.g., JPAP and DWPI Abstracts).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a therapeutic anti-viral *Lentinus edodes* (shiitake) mycelium extract via the instantly claimed steps, including formulating such therapeutic extracts into conventional pharmaceutical, drink, and/or oral (e.g., food) preparations, as well as to treat bacterial infections (such as those instantly claimed), based upon the beneficial teachings provided by the cited Nagaoka reference with respect to such anti-bacterial activity. Please note that the other claim limitations (e.g., that the extract has a particular cell functional activity and/or that it comprises approximate ranges of various ingredients therein) would be intrinsic to the *Lentinus edodes* mycelium extract taught by JP 61103816. The result-effective adjustment in conventional working conditions/parameters (e.g., providing such an extract within one or more conventional pharmaceutical formulations such as those instantly claimed and/or treating a particular type of bacterial infection - especially given that no demonstrated working examples have been provided within the instant disclosure with respect to treating a particular type of bacterial infection, including those instantly claimed) is deemed merely a matter of judicious

selection and routine optimization which is well within the purview of the skilled artisan having the cited references as a guide.

Thus, the invention as a whole is *prima facie* obvious over the cited reference, especially in the absence of evidence to the contrary.

Applicants' arguments (presented within the response filed 06 June 2006) as they pertain to the above art rejections have been carefully considered but are not deemed to be persuasive of error in the rejections.

Applicants argue that the Nagaoka US '615 reference has been misinterpreted by the examiner with respect to the recitation therein: "their *Lentinus edodes* (shitake) mycelium extract is effective as an anti-tumor agent ...". That is, this section (col 1, lines 30-44) of the reference that the Examiner relies upon in US '615 refers to the prior art preparation not the preparation of the Nagaoka '615 inventors. However, this section begins with the recitation "The effect of the bagasse of the culture medium used in this method is described ..." in the prior art teaching (by Gann) which clearly indicates that Nagaoka et al. intend for their composition to also provide such an anti-tumor effect as described by the prior art. Further, the cited prior art teaching therein (i.e., Gann) would clearly suggest to the skilled artisan to use the invention described by Nagaoka et al. in such a manner (i.e., as an anti-tumor agent). Applicants further argue that there is no disclosure in the Nagaoka '615 and '330 references that the extract of *Lentinus edodes* mycelium has anti-tumor activity. The examiner has already discussed the teaching of the Nagaoka '615 reference concerning anti-tumor activity. With respect to the teaching of US '330, as discussed in the art rejection above, this reference teaches a *Lentinus edodes* mycelium

extract, prepared via the same (or essentially the same) steps as instantly claimed, which is useful against liver cancer (see, e.g., claim 5). Accordingly, the cited Nagaoka references teach (or at least reasonably suggest) that their *Lentinus edodes* mycelium extract preparations have anti-tumor activity. Applicants also argue that there must be some suggestion to one skilled in the art of the necessary modifications to achieve the invention. However, as noted immediately above with respect to the US '615 and US '330 references, if not expressly taught therein, these references at the least clearly suggest to the skilled artisan to use the invention described by the Nagaoka references in such a manner (i.e., as an anti-tumor agent. It is reemphasized that other claim limitations (e.g., that the extract has a particular *in vivo* functional cell activity) would be intrinsic to the administered anti-tumor *Lentinus edodes* mycelium extracts taught and/or suggested by US '615 and US '330. Applicants further argue that the US '615 reference (at col 6, lines 35-44) teaches that several different enzymes can be used and, therefore, the Examiner is improperly picking and choosing only select portions of this reference teaching; and further, that the mechanism of the instant invention is through a different underlying functional effect than the prior art. However, as discussed in the previous Office action (in response to Applicants 28 July 2005 arguments), the US '615 reference clearly discloses that cellulase, protease, and/or glucanase can be used to prepare the *Lentinus edodes* mycelium extract therein, and therefore, one of ordinary skill in the art would clearly discern that any one of these enzymatic steps would appropriately provide such an anti-tumor extract composition. Please note that the argued underlying *in vivo* functional effect is not deemed to lend patentable distinction to the claimed method since such an underlying effect would be intrinsic to such an extract as well as within such a method as instantly claimed (i.e., treating a tumor therewith).

With respect to the Nagaoka JP '816 reference, Applicants argue that although this reference teaches that the *Lentinus edodes* extract has antibacterial activity (as noted by the Examiner), the antibacterial activity was determined using the minimum inhibitory concentration ("MIC") method, which is a direct method of measuring the inhibition of bacterial growth by the product - this the MIC method cannot determine whether there is any indirect antibacterial activity of the product via, e.g., enhancement of immune activity by the product. However, as discussed above, the argued underlying *in vivo* functional effect is not deemed to lend patentable distinction to the claimed method since such an underlying effect would be intrinsic to the administered antibacterial *Lentinus edodes* extract composition clearly suggested by he JP '816 reference.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher R. Tate
Primary Examiner
Art Unit 1655